

FDA censures NEJM editor

Scott Gottlieb *New York*

The newly appointed editor of the *New England Journal of Medicine* has been criticised by the US Food and Drug Administration (FDA) for overpraising a new asthma drug made by a company that he had advised as a paid consultant.

Dr Jeffrey Drazen said his error had been an honest one and vowed he has learnt from it. "We were probably a little overzealous," said Drazen, a prominent asthma researcher and chief of the pulmonary division at Brigham and Women's Hospital in Boston, who is scheduled to take the helm of the medical journal in July. "In the future, we'll be more careful," he said.

Drazen's statement comes after news reports that the FDA had last year issued a "notice of violation" against Sepracor, the maker of the pulmonary drug levalbuterol. The FDA had found that Drazen was guilty of making "false or misleading" statements about the value of the drug, according to the original letter. Having been paid by

the firm to evaluate studies on its drug, Drazen concluded that the product was "the first real advance in rescue asthma therapy in over 20 years," the FDA letter said. But the FDA found the statement overstated both the safety and the efficacy of the drug. It said the studies evaluated by Drazen found the drug to be about the same as albuterol in terms of efficacy and only slightly better in terms of side effects. Sepracor used Drazen's ambitious statements to aggressively promote the drug.

In an interview with the *Boston Globe* on 30 May, Drazen said he found the data "very interesting ... highly significant" from a scientific viewpoint. But he conceded that the clinical findings were insignificant. The statement about the drug being the first real advance in 20 years "wasn't quite right," he said. "But I was interested in the science," he said. "I thought it was an advance. But from a purist's point of view, it was not." Drazen said the statement was fine for a scientific meeting but not for marketing. "I'm a scientist first, not a drug marketer," he said. "But I'm wiser for it, and I think I'll be a better editor for it."

"I think the disconnect between money and individual should extend also to researchers," said Dr Timothy



Dr Jeffrey Drazen: criticised by FDA for overpraising asthma drug

Johnson, a physician and chief medical correspondent for *ABC News*. "I personally believe there must be a strong firewall between any money from industry and the research being supported by such money," Johnson said.

When he took the job of editor of the *New England Journal of Medicine* last month, Drazen was immediately criticised for his close ties with several pharmaceutical companies that have funded his pulmonary research and hired him as a consultant. Under the journal's rules on conflict of interest, he is barred from writing editorials or review articles relating to his research or related work within two years

of accepting commercial funding. Outgoing interim editor Dr Marcia Angell lashed out at doctors who place profits first in a journal editorial on 18 May entitled "Is academic medicine for sale?"

Drazen has had financial ties with at least 21 drug firms since 1994, according to several reports. After the most recent disclosure, he said he realises that the issue of conflict of interest is an important one but that academic researchers must continue to work closely with drug companies if they want to see new drugs come to market. "There's no way around it," he said. □

Blair chairs UK health summit to tackle NHS reform

Judy Jones *London*

A summit chaired by the prime minister, Tony Blair, has agreed key priorities for modernisation of the NHS amid angry claims from doctors' leaders that their profession has been made a scapegoat for failures in the service.

Health ministers from the English government and the devolved assemblies in Scotland, Wales, and Northern Ireland met Mr Blair and his advisers for two hours on 5 June to exchange ideas for improving health care.

Among the priorities agreed were to develop measures to end "postcode rationing," which is created by regional variations in the provision of health services; to take steps to improve

coordination between health authorities and social services to free up hospital beds occupied by patients who need care and support in the community; and to plan better for winter peaks in demand.

The action agreed will form part of the government's 10 year blueprint for reforming the NHS, due to be published in July. A public consultation exercise is also under way; 12 million questionnaires have been distributed to users of the NHS asking them to indicate how they would like the service to change.

The summit was partly overshadowed by a fierce political row between doctors' leaders and Alan Milburn, the health

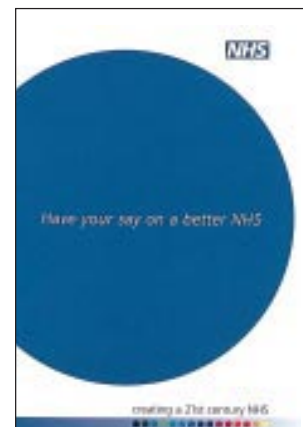
secretary for England, who asserted that the reform programme must tackle the "consultant is king" culture in the NHS. He insisted that the investment of an extra £2bn (\$3.2bn), earmarked this year for better health care, must coincide with a radical overhaul in working practices.

The NHS Confederation, which represents managers, has also called for the development of more patient oriented staffing of the service, in place of the "professional tribalism" which it believes often dominates current arrangements. It wants a new pay structure and the reform of consultants' merit awards, which it believes to be outdated.

Dr Ian Bogle, chairman of the BMA, accused the health secretary of "constantly seeking to set doctors against nurses, and doctors against patients." He added: "If the government wants to get the best out of the medical profession it should

recognise that value rather than denigrate it."

Mr Milburn later adopted a more conciliatory tone when he responded to the BMA's onslaught. "The government recognises that the overwhelming majority of consultants do a brilliant job for the NHS," he said. □



12m questionnaires distributed